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An Analysis of New Drug Examination and Approval System of PRC

Xiaopu Sun

April 29, 2008

Food and Drug Law

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Introduction

Zheng Xiaoyu, the former director of National Food and Drug Administration of the PRC was executed in Beijing on July 10, 2007. From June 1997 to December 2006, Zheng Xiaoyu had accepted bribery from eight pharmaceutical companies while examining and approving their drugs and medical devices. In addition, from 2001 to 2003, Zheng Xiaoyu had illegally lowered the standard of examining and approving drugs, which resulted many unqualified drugs being approved. It was later discovered that six of the approved drugs are counterfeit drugs.¹ The case of Zheng Xiaoyu raised great public attention on the issue of drug safety. Both the voices from academia and government called for reform and improvement of the drug regulation system, especially the new drug regulation system, viz. new drug examination and approval.

The new drug examination and approval system was established in the Pharmaceutical Administration Law which was issued by the Standing Committee of National People's Congress and elaborated in the Measures for the Administration of Drug Registration (hereinafter referred as "the Measures") which were promulgated by the State Food and Drug Administration (hereinafter referred as "SFDA") on May 1, 2005. The Measures have the same function in China as regulations do in the

¹ Xin hua wang [Xinhua Net], Jing zui gao Renmin Fayuan he zhun Zheng Xiaoyu 10 ri Shangwu bei zhi xing Sixing [Approved by the Supreme Court, Zheng Xiaoyu was Executed in the Morning of the 10th] (July 10, 2007), http://news.xinhuanet.com/legal/2007-07/10/content_6353841.htm.

United States. On October 1, 2007, the Measures were amended (hereinafter referred as the “2007 Amendment”), which brought significant changes to the new drug examination and approval system.

Abstract

This paper analyzes the new drug examination and approval systems before and after the Measures was amended in 2007 and evaluates the effectiveness of the 2007 Amendment.

In Part One, this paper introduces the new drug examination and approval system before the Measures were amended in 2007 and analyzes its disadvantages. Part Two of the paper describes the changes brought by the 2007 Amendment to the Measures and evaluates their effectiveness with regard to drug safety. Part Three discusses the impacts of the Agreement between the Department of Health and Human Services of the United States of America and the SFDA of the People's Republic of China on the Safety of Drugs and Medical Devices on Chinese new drug regulation system. In the end, the author concludes that although the tendency of stricter supervision of government authority is obviously beneficial for the guarantee of drug safety, the effective implementation of the legal schemes is still a big issue in China.

Part One: The New Drug Regulation System before the 2007 Amendment

The main statute establishing the new drug regulation system is the Pharmaceutical Administration Law. It was adopted by the Seventh Session of the Standing Committee of the Fifth National People's Congress on September 20, 1984, implemented on July 1, 1985, and then amended at the Twentieth Meeting of the Standing Committee of the Ninth National People's Congress on February 28, 2000 and entered into force as of December 1, 2001. Article 31 of the Pharmaceutical Administration Law of the PRC requires that the production of new drugs shall be approved by the drug supervision and administration agency in State Council,² which implements the drug approval system in China. "The drug supervision and administration agency in State Council authorizes the drug, medical and other technical experts to review the new drugs."³

The provisions on the new drug registration system in the Pharmaceutical Administration Law are very vague and abstract. Therefore, the SFDA promulgated the Measures which became effective on May 1, 2005. The Measures provide a concrete scheme of new drug examination and approval. According to the Measures, the application for new drugs includes "the applications for the registration of drugs that have not been marketed within China,"⁴ In addition, "if the type of preparation or the route of administration of any drugs that have been marketed is changed, or if the range of indications thereof is newly expanded, the said drugs shall be treated as new

² Pharmaceutical Administration Law (promulgated by the Standing Comm. National People's Cong., Feb. 28, 2001, effective Dec. 1, 2001), art. 31, translated in CHINALAWINFO (last visited April 5, 2008) (P.R.C.).

³ *Id.* Art. 33.

⁴ Measures for the Administration of Drug Registration (promulgated by the State Food and Drug Administration, Feb. 28, 2005, effective May 1, 2005), art. 8, sec. 1, translated in CHINALAWINFO (last visited April 5, 2008) (P.R.C.).

drugs.”⁵ Therefore, the scope of a new drug application is relatively broad under the Measures. Because the applications are filed in writing, the Measures require that “the materials submitted for the registration of new drugs shall be complete and normative, and the data must be true and reliable.”⁶ The Measures also include a series of requirements on the examination and approval of clinical trials and manufacture of new drugs.

I. Examination and Approval of Clinical Trials of New Drugs

The examination and approval of clinical trials of new drugs is an important component of new drug regulation. While applying for the registration of a new drug, an applicant is required to conduct clinical trials, which are classified into four phases: I, II, III and IV. Generally speaking, phases I, II, and III clinical trials shall be conducted before a new drug is approved for marketing.⁷

The phase I clinical trial: the preliminary trials on clinical pharmacology and human body safety evaluation, which aim to observe the degree of tolerance of human body against the new drug and the drug dynamics, and provide the basis for working out the dosage administration scheme.

⁵ *Id.*

⁶ *Id.* Art. 47.

⁷ *Id.* Art. 24, Sec. 2. (Under certain circumstances, the applicant may, upon approval, only conduct phases II and III clinical trials or only phase III clinical trials.)

The phase II clinical trial: the preliminary evaluation of the treating effects, which aim to preliminarily evaluate the treating effect and safety of the drug on the target patients with the applicable disease, and also to provide the basis for the determination of the study design and dosage administration scheme for the clinical trials in phase III.

The phase III clinical trial: the confirmation phase of the treating effect, which aims to further verify the treating effect and safety of the drug on the target patient with the applicable disease, to evaluate the relationship between benefit and risk, and to eventually provide an adequate basis for the examination of the drug registration application.

The phase IV clinical trial: the phase of application study conducted by the applicant independently after the new drug comes into the market, which aims to examine the curative effect of the drug and the adverse reactions when it is widely used, to evaluate the relationship between benefit and risk when the drug is used in ordinary or special groups and to improve the dosage, administration, etc.⁸

Because of the importance and impact of clinical trials, the Measures provides the

⁸ *Id.* Art. 24.

application and review procedures before conducting clinical trials.

First, “an applicant shall fill in the Application Form for Drug Registration, and faithfully submit the relevant materials and drug samples to the local (food) drug administration of the province, autonomous region or municipality directly under the Central Government after finishing the pre-clinical trial of new drugs.”⁹ The examination and approval of clinical trials of new drugs is composed of formal and substantial reviews. The (food) drug administrations of the province, autonomous region, or municipality directly under the Central Government which are in charge of the examination of the application materials shall conduct a formal review of the application materials. “If the application materials meet the relevant requirements, it shall accept them and give the applicant an application acceptance notice. If they do not meet the relevant requirements, it shall give the applicant a rejection notice of application with corresponding explanation.”¹⁰

Besides the review of application materials, the (food) drug administrations of the province, autonomous region or municipality directly under the Central Government also conduct on-spot inspections before approving to carry out clinical trials. They shall organize an on-spot inspection “within 5 days after they accept the application, take 1-3 samples for inspection use and send a notice about the registration inspection

⁹ *Id.* Art. 52.

¹⁰ *Id.* Art. 53, Sec. 1.

to the designated institute for drug control.”¹¹ In the end, they shall also “submit the examination opinions, inspection report and application materials to the State Food and Drug Administration and notify the applicant within the prescribed time limit.”¹² The institute for drug control which receives the notice about registration inspection from the drug administrations will then “check and test the samples, verify the drug standards of the application, and submit the inspection report and verification opinions to the SFDA, the (food) drug administrations of the province, autonomous region, or municipality directly under the Central Government which sent the inspection notice to it, and the applicant.”¹³

At this time, all the relevant materials and information are held by the SFDA, which is in charge of conducting the substantial review of the application. The SFDA organizes technicians of pharmacology, iatrology and other subjects to conduct technical evaluation of the new drug. If it believes that the applicant meets the pertinent provisions, it shall issue it an Approval of Drug Clinical Trial. Otherwise, it shall give it a Notice of Examination Opinions with corresponding explanation.¹⁴

One critical issue in the review process for clinical trials is the controllability of the quality of the new drug. The following requirements apply to the clinical trials. If the institute for drug control considers that the drug standards applied are unable to

¹¹ *Id.* Art. 53, Sec. 2.

¹² *Id.*

¹³ *Id.* Art. 54.

¹⁴ *See Id.* Art. 55.

control the quality, the applicant may withdraw the new drug application. If the applicant fails to withdraw its application and later the SFDA considers that the drug standards are really unable to control the quality, the application will not be approved.¹⁵ In order to get approval, the samples taken from the on-spot inspection shall also meet relevant drug standards. “If, upon inspection, any sample does not conform to the drug standards for which the applicant applies, the SFDA shall disapprove the new drug application.”¹⁶

The examination of an application for new drug registration should be generally based on materials submitted in the beginning. The only exceptions provided in the Measures are for “the creative ingredients of the drug or new discoveries involving the drug safety.”¹⁷ Otherwise, the applicant shall not supplement the original application with any new technical materials. “If the applicant insists that it must supplement some technical materials, it shall withdraw its drug registration application and file a new one after it has prepared a complete set of materials.”¹⁸

II. Examination and Approval of the Manufacture of New Drugs

After finishing the clinical trials of drugs, it is time to file an application for new drug

¹⁵ *See Id.* Art. 56.

¹⁶ *Id.* Art. 57.

¹⁷ *Id.* Art. 58.

¹⁸ *Id.*

registration. This is also the phase when a lot of corruption and fraud happens.

According to the Measures,

an applicant shall fill out an Application Form for Drug Registration, submit the clinical trial materials and other modified and supplemented materials to the (food) drug administration of the province, autonomous region or municipality directly under the Central Government where it is located, explain the basis and reasons in details, and send the raw materials of the standard products to the National Institute for the Control of Pharmaceutical and Biological Products at the same time.¹⁹

The examinations conducted by the (food) drug administration of the province, autonomous region, or municipality directly under the Central Government are also composed of formal and substantial examinations. First of all, it shall conduct a formal examination over the application materials. If it considers that the application materials meet the relevant requirements, it shall accept them and issue to the applicant a notification of acceptance of the drug registration application. Otherwise, it shall reject them and issue to the applicant a notice of rejection of the drug registration application with corresponding explanation.²⁰ Then, being similar to the requirements in examination and approval of clinical trials, the (food) drug administration of the province, autonomous region or municipality directly under the

¹⁹ *Id.* Art. 60.

²⁰ *See Id.* Art. 61.

Central Government shall also organize an on-spot inspection “within 5 days after it accepts an application, select samples from the products of 3 successive production batch numbers, send a registration inspection notice to the designated institute for drug control, and submit the examination opinions, investigation report and application materials to the SFDA and notify the applicant.” ²¹

In the end, the SFDA will conduct the substantial examination and make the final decision based on whether the application materials meet the relevant requirements. If it considers that the application materials meet the relevant requirements, it shall issue the applicant an Approval Document on Drug Registration and a New Drug Certificate. If the applicant holds a License for Drug Manufacturing and have the conditions for manufacturing the drug, the SFDA may simultaneously issue to the applicant the registered number of drug approval. If SFDA considers that the application materials do not meet the relevant requirements, it shall issue to the applicant a Notice about the Examination Opinions with corresponding explanation.²²

Based on the description above, it is of no doubt that the State Food and Drug Administration is extremely powerful in the process of new drug examination and approval. It possesses the sole authority to make substantial decisions on new drug applications. The broad and apparently unlimited power unavoidably leads to the abuse of power and severe corruption.

²¹ *Id.* Art. 62.

²² *See Id.* Art. 65.

III. Administration of the Monitoring Periods of New Drugs

The Measures provide another important mechanism for the protection of public health: the monitoring period of new drugs. “In order to protect public health, the SFDA may set forth monitoring periods for new drugs approved to be manufactured, to continually monitor the safety of those new drugs. The SFDA will not approve other enterprises to manufacture or import new drugs within the monitoring periods.”²³

The monitoring period of a new drug shows the government’s concern and caution on the impact of the new drugs on public health and safety. According to the Measures, it is determined “on the basis of the existing safety research materials and the research status domestically and abroad. In addition, it shall not exceed 5 years from the date of approval of manufacturing the drug.”²⁴ For a new drug, within the monitoring period the drug manufacturing enterprise carries a heavy burden on the inspection of drug manufacture. It shall “regularly inspect the manufacturing techniques, quality, stability, curative effect and adverse reactions, etc., and make a report each year to the (food) drug administration of the province, autonomous region or municipality directly under the Central Government where it is located.”²⁵ The Measures also have

²³ *Id.* Art. 68.

²⁴ *Id.* Art. 69.

²⁵ *Id.* Art. 70.

requirements on immediate reporting to the relevant government agency when “any of the entities relating to the manufacturing, operation, use, or inspection or supervision of drugs finds that the new drug has any serious quality problem, or causes any serious or unanticipated adverse reactions.”²⁶

Another important impact of the monitoring period is on the identical registration application filed by other applicants. The Measures provide that “from the day when a new drug enters the monitoring period, no identical registration application filed by any other applicant may be accepted.”²⁷ This provision is also beneficial for the public health in case potential adverse reactions are caused by the new drugs within the monitoring period.

IV. Legal Liabilities

The Pharmaceutical Administration Law includes a series of provisions on legal liabilities of the government officials. If government officials abuse their authority to such an extent that a crime is committed, they shall be investigated for criminal liabilities. If their acts have not constituted a crime, they shall be subject to administrative sanctions.²⁸ Article 203 of the Measures provides that

²⁶ *Id.*

²⁷ *Id.* Art. 75.

²⁸ *See* Pharmaceutical Administration Law, art. 99, translated in CHINALAWINFO (last visited April 5, 2008) (P.R.C.).

“if the SFDA, or the (food) drug administrations of a province, autonomous region or municipality directly under the Central Government, or any of its staff member extorted or accepted any property of others or seek other benefits, he should be punished according to the Administrative License Law, which provides that for any of the functionaries who asks for or accepts the property of others’ or seeks for other interests when implementing an administrative license and exercising supervision and inspection, if he constitutes a crime, he shall be subject to criminal responsibilities; if the violation does not constitute a crime, he shall be given an administrative sanction in accordance with the law.”²⁹

Although there are clear provisions on legal liability in the laws and regulations, they are ignored when the government officials are endowed broad authority without corresponding supervision mechanisms. It is always the case that unlimited authority is the soil for the growth of corruption. According to the Pharmaceutical Administration Law, the examination and approval authority of new drugs is substantially delegated to the national drug administration, viz. State Food and Drug Administration and provincial drug administrations. This system is beneficial when there is highly efficient supervision, but it opens the door to bribery and corruption when the significant authority is controlled by high level government officials. As we can see in the Zheng Xiaoyu Case, because there are not sufficient supervision

²⁹ *Id.* Art. 73.

mechanisms on the authority of government officials, the new drug examination and approval system is subject to the potential for serious corruption.

Part Two: Reforms in the 2007 Amendment

After the Zheng Xiaoyu Case, the Chinese central government became highly concerned with the issue of new drug regulation. Because of its significant impact on public health and safety, this topic also attracted broad public attention. In order to relieve public worry about drug safety, the National Drug Administration declared on January 15, 2007 that all the drugs in the market must be approved again. Any drug which can not pass the examination has to be withdrawn from the market.³⁰

Systematic reform was also on its way. The Measures were amended on October 1, 2007. The 2007 Amendment covers many adjustments to the new drug examination and approval system. In the context of structural reform, it added the chapter of “Basic Requirements for Drug Registration”, and deleted “Application of Drug Registration” and “Pre-Clinical Research of Drugs” etc. Although the 2007 Amendment does include other issues besides the reform of new drug regulation, this paper will only elaborate the amendments to the new drug examination and approval system.

³⁰ Renmin Wang [Renmin Net], Guo jia yao jian ju yuan fu ju zhang Zheng Xiaoyu an fa jia su shen pi zhi du gaige [Zheng Xiaoyu Case Promoted the Reform of the Examination and Approval System] (January 29, 2007), <http://politics.people.com.cn/GB/1026/5336605.html>.

I. Narrower Scope of the New Drug Application

The 2007 Amendment narrowed the scope of the new drug application to “the applications for the registration of drugs that have not been marketed within China.”³¹

The old definition also included the drugs, “the type of preparation or the route of administration of which is changed, or the range of indications is newly expanded.”³²

Under the old definition, a large number of new drug applications were filed to the National Food and Drug Administration every year. It is an overwhelming burden on the agency, considering its limited personnel and resources. What is more, some pharmaceutical companies took advantage of this provision and obtained a number of new drug approvals for the same drug. In this way, they raised the price of the drug and got illegal benefit by cheating on uninformed consumers. Therefore, the amendment to the definition of “new drug application” is beneficial both to the drug supervisory agency and the public.

II. Stricter New Drug Examination and Approval Procedures

³¹ Measures for the Administration of Drug Registration, art. 12, translated in CHINALAWINFO (last visited April 5, 2008) (P.R.C.).

³² *Id.* Art. 8, Sec. 1.

The requirements of new drug examination and approval procedures are stricter. Chapter Four of the Measures specifically provides for the application and approval of new drugs.

The amendment introduces more mechanisms to ensure the authenticity of the application materials. According to the Amendment, “the applicant shall provide reliable research data to prove the safety, effectiveness and controllability of the quality of the drug. The applicant should be responsible for the authenticity of all the materials.”³³ What happened in the past was that a lot of fake application materials were filed to the drug administration and were approved. The Amendment put more responsibility on the applicants in this aspect. However, without efficient supervision, the applicants will not have any incentive to follow the statutory requirements. Therefore, in contrast to the former process which largely relied on reviewing written materials, the Amendment stresses the importance of on-spot inspection. In the process of new drug examination, the drug supervision and administration agency should conduct on-spot inspections of non-clinical research and clinical research, and an on-spot inspection of production before approval for marketing in order to guarantee the authenticity, veracity and complicity of the application materials.³⁴ This mechanism is intended to discover possible fraud in the application materials and supervise compliance of the pharmaceutical companies.

³³ *Id.* Art. 13.

³⁴ *Id.* Art. 16.

III. More Supervision on Government Authority

The most significant amendment is the restriction and supervision on examination and approval authority. Unlimited authority is the unavoidable source of corruption and malpractice. In order to prevent the abuse of authority by government officials in the process of the examination and approval of new drugs, three mechanisms are provided in the Amendment, including the Chief Umpire and Collective Responsibility System, Public Notification of Related Personnel and Publicity of all the Procedures of Examination and Approval.³⁵ The provision on the Chief Umpire and Collective Responsibility System ended the era when a single chief official could make all the decisions. The introduction of collective responsibility is intended to bring more supervision to the examination and approval authority held by the administrative agencies. Public Notification of Related Personnel and the Publicity of all the Procedures of Examination and Approval will make the government procedures more transparent and bring in more public participation and supervision. The government opened information to the public and promoted public supervision of the authority of the government officials. The three mechanisms definitely help to avoid and supervise the abuse of government authority.

One of the major reasons why corruption in the new drug examination and approval system became such a huge problem is because of the lack of transparency in this

³⁵ *Id.* Art. 6.

process. Although there is no clear provision in the Amendment about the public availability of information, new regulation titled the Provisions on the Disclosure of Government Information was adopted at the 165th standing meeting of the State Council on January 17th, 2007, and should come into force as of May 1st, 2008. The term “government information” as mentioned in this regulation refers to “information produced or acquired and recorded or kept in certain forms by administrative agencies in the process of performing their responsibilities.”³⁶

There are two ways for government information to be disclosed according to this regulation. One way is called “Voluntary Disclosure.” One category of information which the government shall voluntarily disclose is about “issues subject to administrative approval including the corresponding basis, requirements, quantity, procedures, time limit and list of all the materials that shall be submitted for purposes of administrative approval.”³⁷ It is obvious that this category covers the new drug approval information held by the government. Therefore, the new drug approval information is required to be disclosed by the government agencies “within 20 workdays of the day when such government information is formed or changed, unless there is any different requirement stipulated by other laws or regulations on the time limit for government information disclosure.”³⁸

³⁶ Provisions on the Disclosure of Government Information (promulgated by the State Council, Jan. 17, 2007, effective May 1, 2008), art. 2, translated in CHINALAWINFO (last visited April 5, 2008) (P.R.C.).

³⁷ *Id.* Art. 10.

³⁸ *Id.* Art. 18.

The other way is called “requested disclosure.” In addition to the government information voluntarily disclosed by government agencies, citizens and organizations may apply for disclosure of other government information. They may “in light of their special needs for manufacture, living or scientific research, etc., apply to the national departments under the State Council, the local governments at various levels and the departments of the local governments at or above the county level for access to government information.”³⁹ Although this provision is very vague, it provides another venue to obtain relevant government information. Even if the government agencies decide that the government information shall not be disclosed, the applicant shall be given reasons for the denial. If the request for information disclosure was filed with the wrong agency, the agency shall notify the applicant of this fact and provide the name and contact information of the government agency which the applicant shall request for information if possible. Even when the requested information does not exist, the applicant is also entitled to be notified of this fact.⁴⁰

One possible barrier to get information disclosed lies in the protection of commercial secrets. “No government agency may disclose any government information involving state secrets, commercial secrets or individual privacy. However, in cases where the rights holder consents or when the government agency believes that the failure to disclose such information would impair public interests, such government information

³⁹ *Id.* Art. 13.

⁴⁰ *See Id.* Art. 21.

may be disclosed.”⁴¹ Commercial secrets may be involved in the materials for new drug examination and approval. However, considering the intimate relationship between drugs and public health and safety, it would be a very strong argument that failure to disclose such information would impair the public interest.

If the government refuses to disclose the information, there are legal remedies provided in the regulation. There are supervisory agencies which are responsible for the investigation of malpractice in government agencies. “Where any citizen, legal person or any other organization believes that a government agency fails to fulfill its obligation to disclose information according to the law, he/it may inform the superior government agency, supervisory organ or the competent department dealing with government information disclosure.”⁴² The citizen, legal person, or organization which informs the supervisory agency does not need to prove any connection with the disclosure of information. If they believe that their legal interest has been impaired by an administrative act, they can file an administrative lawsuit for judicial review of the agency action.⁴³ If the government agency fails to respond to the application for information disclosure, the applicant can file an administrative lawsuit in Chinese court. It is good to see that the publicity requirement in the amended regulation does invite the possibility of public participation and supervision.

⁴¹ *Id.* Art. 14.

⁴² *Id.* Art. 33.

⁴³ *Id.* (If any citizen, legal person or any other organization believes that a concrete administrative act committed by an government agency in carrying out government information disclosure work has infringed upon his/its legal rights and interests, he/it may apply for administrative reconsideration or bring an administrative lawsuit according to law.)

IV. Evaluation of the Effectiveness of the 2007 Amendment

Despite all the wonderful improvements in the amended regulation, there are still questions left about the effectiveness of the new mechanisms. A declarational provision in the law or regulation is not enough to make an effective legal mechanism. In order to guarantee that government officials will faithfully follow the requirements in the laws and regulations, it is very important to include a strong legal accountability system for government officials.

Under the current system, the supervisory agencies within the administrative branch take main responsibility for supervising government officials. According to prior experience, because the supervisory agencies are not independent from the administrative branch, their supervision has been quite limited. The supervisory agencies need an independent status to fully exercise their authority. Otherwise their supervision can be seriously affected by the administrative agencies. An efficient supervision system can disclose illegal behavior of government officials at an early stage, which could reduce the damage caused to the public and save the great expense of public advocacy or litigation. Therefore, an independent and efficient supervisory branch would be a powerful mechanism against corruption.

On the other side, public supervision is also a powerful tool. The disclosure of

government information serves as the first step to the process of public participation. Because the Provisions of on the Disclosure of Government Information is a newly issued regulation, there is not enough experience to evaluate its effectiveness under the current system. Still it shows the determination and intention of the Chinese government to encourage public participation and supervision. With the involvement of the public, government officials will definitely become more careful while performing their responsibilities. Another major issue for public participation is to build up the participation capacity of the public. If the public is not capable of substantially supervising the government, the relevant legal schemes provided in the laws and regulations would become useless. One common way to build up public capacity and promote public participation is through the non-government organizations. In contrast to the robust non-government organizations in the US, the domestic non-government organizations in China have less access to intellectual and financial resources, which make organized public participation very difficult. Even though the public can get access to government information, how to make good use of it is still a huge challenge for them. Therefore, legal reform and the rule of law in China still have a long way to go both in the legal system and public capacity building.

Part Three: China-U.S. Cooperation on Drug Regulation

In addition to domestic efforts, the Chinese government also seeks to obtain international support and cooperation. On December 11, 2007, the SFDA of the People's Republic of China and the Department of Health and Human Services of the United States of America signed the Agreement on the Safety of Drugs and Medical Devices (hereinafter referred as "the Agreement"). The two parties understand the mutual benefits of protecting the public health through improved cooperation between the parties with regard to monitoring and regulating the safety of drugs and medical devices, and desire to work together to better ensure the safety and quality of drugs, excipients, and medical devices.⁴⁴

The Agreement establishes a list of designated drugs and designated medical devices and requires registration and collaboration on them. This mechanism is designed to help protect the safety of imported/exported drugs and medical devices. The requirements for SFDA can also promote the systematic development of drug regulation in China. For example, according to the Agreement, "HHS/FDA shall consult with SFDA to assist SFDA in understanding HHS/FDA Requirements for

⁴⁴ Agreement between the Department of Health and Human Services of the United States of America and the State Food and Drug Administration of the People's Republic of China on the Safety of Drugs and Medical Devices, available at http://www.fda.gov/oia/agreements/China_Drugsdevices.htm.

Designated Drugs and Designated Medical Devices.”⁴⁵ In this way, SFDA can get access to HHS/FDA’s relevant technological information and regulatory scheme, and improve its own regulatory arrangements. HHS/FDA and SFDA will cooperate on identifying plausible and effective means to ensure the quality, safety, and authenticity of designated drugs.⁴⁶ The joint effort between the two agencies will consequently contribute to the reform of the Chinese drug regulation system. In order to ensure the performance of responsibilities under the Agreement, documentation is required by the Agreement. “SFDA shall maintain documents on file related to reviews, inspections, testing, recalls, compliance, and any other assessment of a Firm of Designated Drugs and Designated Medical Devices.”⁴⁷ This provision puts more burdens on SFDA to modernize and regularize its administrative actions.

The Agreement is not only intended to promote understanding between the parties and recognize the differences between their systems, but also to address those differences and gaps.⁴⁸ Specifically, “SFDA shall actively create conditions to enable SFDA to certify that HHS/FDA Requirements are met for firms producing Designated Drugs and Designated Medical Devices intended for export to the United States.”⁴⁹

Another cooperative aspect in the Agreement is information sharing between the

⁴⁵ *Id.* Article IV, B.

⁴⁶ *Id.* (HHS/FDA and SFDA shall review the HHS/FDA Requirements for the Designated Drugs and Designated Medical Devices and the SFDA Requirements for the Designated Drugs and Designated Medical Devices to understand the differences and identify the means to ensure the quality, safety, and authenticity of Designated Drugs and Designated Medical Devices.)

⁴⁷ *Id.*

⁴⁸ *Id.* Article IV, C. (The Parties agree to pursue activities to better understand the differences and the gaps between HHS/FDA and SFDA requirements and establish mechanisms to address those gaps.)

⁴⁹ *Id.*

parties. “The Parties shall exchange information related to Drugs, Excipients, and Medical Devices and their respective regulatory systems concerning Drugs, Excipients, and Medical Devices on a timeframe.”⁵⁰ Given access to the information about the regulatory systems by HHS/FDA, SFDA will be more active and creative in the reform and implementation of China’s new drug regulation system.

Besides all the cooperative schemes mentioned above, the concrete regulatory cooperative activities proposed in the Agreement will also have a profound impact on Chinese drug regulation system in the long term. The regulatory cooperative activities include “training programs and scientific discussions or cooperation, intended to support the long term stability and effectiveness of the registration and certification programs.”⁵¹ Some of the appropriate regulatory cooperative activities are listed in the Agreement, such as:

development and coordination of the training programs for Chinese inspectors; technical exchanges and training relating to the use of Good Clinical Practice (GCP) to ensure the safety of human subjects and the collection of valid clinical data; and training and exchange on the development of evaluation review methods, inspection techniques, establishment of computer databases, evaluation report standard formats, and the development of technical guidance documents, and laws and

⁵⁰ *Id.* Article V.

⁵¹ *Id.* Article VI.

regulations.⁵²

Cooperation is also reflected in the promulgation process for relevant regulations. Before a regulation related to a designated drug is issued, the Agreement requires an open comment period. “Except in extraordinary circumstances . . . each Party shall publish on its website(s) all proposed regulations and other measures related to Designated Drugs and Designated Medical Devices and allow a reasonable period of time for all interested parties to submit comments.”⁵³ This provision provides a participation opportunity for all the interested parties. In addition, “each Party shall consider such comments and, at the time final regulations are adopted, address in writing significant, substantive comments received from interested persons during the comment period and explain any substantive revision made to the proposed regulations.”⁵⁴ After this comment and review process, “both Parties shall also publish on its website all final regulations and measures related to Designated Drugs and Designated Medical Devices and allow a reasonable amount of time before implementation and enforcement.”⁵⁵ What is provided in the Agreement is quite similar to the rulemaking process in the U.S., which will increase public participation and transparency in rulemaking.

The Agreement will assist and supervise SFDA on performing its responsibilities for

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

drug regulation, but it has some disadvantages at the same time. Most of its requirements are limited to the designated drugs, which significantly narrows its effect on Chinese drug safety issues. A large number of drugs will not be covered by the Agreement. In addition, it mainly focuses on drugs for export to the US, which neglects the drugs sold within China. In the end, it is not specifically tailored to the new drug regulation process, which is the subject of this paper. Nevertheless, I would still consider the Agreement as a big success for public safety and health. It is great to see the SFDA and HHS/FDA recognize the differences in each country and keep an open mind to technological and regulatory cooperation between them. In the future, SFDA still faces more challenges and will need to maintain domestic and international access to better systems in the long term.

Conclusion

In response to the corruptions cases, the recent reform of the new drug regulation system of PRC has mainly focused on the supervision of government authority by supervisory agencies and the public. The tendency of stricter supervision of government power is obviously beneficial for the drug safety. However, the effective implementation of legal schemes is still a big issue in China. Because the supervisory agencies lack independent status, their supervision is seriously limited by the impact of administrative agencies. On the side of the public, access to sufficient and

authentic government information has not been fully guaranteed under the current system. The capacity of public participation is still under construction. Non-government organizations in China are facing many difficulties with regard to human and financial resources. Judicial reform is still underway to ensure the independence of judicial agencies. Therefore, the issue of drug safety is by all means a very complicated issue which involves both legal and social reform. It will take a long time to realize a substantial transformation.